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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,179

03/02/2004

Peter H. Sayet

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EXAMINER

OU, JING RUI

ART UNIT

PAPER NUMBER

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03/31/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/791,179	Applicant(s) SAYET, PETER H.	
	Examiner JING OU	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22, 25-41, 43 and 66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22, 25-41, 43, and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the amendment filed on 01/09/2009.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 22, 25-41, and 43** are rejected under 35 U.S.C. 102(b) as being anticipated by Hopkins (US 4,458,681).

Hopkins discloses:

22. A non-invasive stomach stricture device, comprising: a front side member (Fig 1 Item 10); a backside member (Fig 1 Item 12); a connector (Fig 1 see marked drawing Item 1 from preceding Office action 9/12/2006) for coupling the front side member to the backside member to form a clamp, wherein the clamp has a substantially u-shaped cross section (a portion of the device has a u-shaped cross-section at item 16) with an open end (the open end of 16), with said front side member and said backside member forming a substantially continuous clamping of the stomach so as to form a canal within the stomach that is an extension of the esophageal canal for regulating nutrient absorption and caloric intake by reducing the capacity of the stomach (Fig 8), and

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wherein the backside member and the front side member include stomach contacting surfaces, the stomach contacting surfaces being free of piercing projections (Fig 1 Items 10 and 12), the connector comprising a clamp adjusting mechanism (24) for adjusting the distance between said front side member and said backside member, said connector further comprising an angularly moveable receiving portion (item 22), said receiving portion being adapted to detachably engage said front side member, such that in one configuration said front side member is completely detached from at least one of said connector and said backside member (figure 1).

25. The device according to claim 24, wherein at least one of the stomach contacting surfaces include structure for permitting fluid flow (Fig 1).

26. The device according to claim 22, further comprising: a positioning member for coupling to the front side member and the backside member to form a clamping assembly (Fig 1 Item 22 opposite of the angularly moveable portion).

27. The device according to claim 22, wherein the front side member, connector, and backside member are integral (Figure 3).

28. The device according to claim 22, wherein the backside member and the connector are integral (Fig 1 Item 15).

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29. The device according to claim 22, wherein the connector comprises a slot adapted to receive the front side member so that the front side member can be coupled to the backside member to form a clamp (Fig 1 Item 15).

30. The device according to claim 26, wherein the backside member and the front side member each comprise an anchoring slot, each anchoring slot adapted to receive an end of the positioning member (Fig 1 Items 14 and 15 on the right side of the figure).

31. The device according to claim 30, wherein each slot and the positioning member include corresponding engagement structure for coupling the positioning member to the front side member and the backside member (Fig 1 Items 14 and 15 and Item 22).

32. The device according to claim 22, wherein the front side member and the backside member include an aperture through which the front side member and the backside member can be sutured to the stomach (Fig 1 Items 14 and 15).

33. A non-invasive stomach stricture device, comprising: a substantially planar front side member (Fig 3 Item 10 shows item to be substantially planar); a substantially planar backside member (Fig 3 Item 12); a connector (Fig 1 see marked drawing Item 1 from preceding Office action 9/12/2006) for coupling the front side member to the backside member to form a clamp, wherein the clamp has a substantially u-shaped cross section (a portion of the device has a u-shaped cross-section at item 16) with an

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open end (the open end of 16), with said front side member and said backside member forming a substantially continuous clamping of the stomach so as to form a canal within the stomach that is an extension of the esophageal canal to limit the rate of flow of ingested material into the stomach and to limit the digestion and absorption of the ingested material (Fig 8), and wherein the backside member and the front side member include stomach contacting surfaces, the stomach contacting surfaces being free of piercing projections (Fig 1 Items 10 and 12), the connector comprising a clamp adjusting mechanism (24) for adjusting the distance between said front side member and said backside member , said connector further comprising an angularly moveable receiving portion (item 22), said receiving portion being adapted to detachably engage said front side member, such that in one configuration said front side member is completely detached from at least one of said connector and said backside member (figure 1).

34. The device according to claim 33, wherein the connector and the backside member are integral (Fig 1 Item 12).

35. The device according to claim 33, wherein the connector determines the distance between the front side member and the backside member (Fig 3).

36. The device according to claim 33, further comprising a positioning member for positioning the stomach stricture device on the stomach of a patient (Fig 1 Item 22).

37. The device according to claim 36, wherein the positioning member couples to a portion of the front side member and to a portion of the backside member (Fig 1 Item 22).

38. The device according to claim 36, wherein the positioning member is adjustable relative to the front side member and the backside member (Fig 1).

39. The device according to claim 37, wherein the backside member and the front side member each comprise an anchoring slot for receiving an end of the positioning member (Fig 1 Items 14 and 15 right side of figure).

40. The device according to claim 39, wherein the positioning member comprises engagement structure for connecting with at least one corresponding engagement structure in at least one of the front side member and the backside member (Fig 1 Item 22).

41. The device according to claim 33, wherein the front side member is separable from the backside member for allowing the device to be removed from a patient (Fig 1).

43. The device according to claim 33, wherein the device is dimensioned for positioning adjacent to the upper quadrant of a human stomach, substantially perpendicular to the

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esophagus, to limit the rate of flow of ingested material into the stomach and to limit the digestion and absorption of the ingested material (Fig 8).

66. A non-invasive stomach stricture device, comprising: a front side member (Fig 3 Item 10); a backside member (Fig 3 Item 12); a connector (Fig 1 see marked drawing Item 1 from preceding Office action 9/12/2006) for coupling the front side member to the backside member to form a clamp, wherein the clamp has a substantially u-shaped cross section (a portion of the device has a u-shaped cross-section at item 16) with an open end (the open end of 16), with said front side member and said backside member forming a substantially continuous clamping of the stomach (Fig 8), and wherein the backside member and the front side member include stomach contacting surfaces, the stomach contacting surfaces being free of piercing projections (Fig 1 Items 10 and 12), the connector comprising a clamp adjusting mechanism (24) for adjusting the distance between said front side member and said backside member.

Response to Arguments

4. Applicant's arguments filed 01/09/2009 have been fully considered but they are not persuasive. The Examiner considers the members to be substantially flat or level as shown in figure 3. It also includes a u-shaped portion. The current claim language does not specifically state that the entirety of the clamp forms a u-shape cross-section, only that it has a cross section of this nature. Because a portion of the clamp includes this feature, the limitation is met by the prior art.

In response to applicant's argument that Hopkins does not disclose that u-shaped clamp is for fitting adjacent the trachea and to form a canal within the stomach that is an extension of the esophageal canal, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The allegation on page 16 of the remarks that Hopkins does not disclose a clamp adjustment for adjusting the distance between the front side member and the back side member is incorrect. Hopkins clearly discloses a clamp adjusting mechanism (spacer sleeves, 24) for adjusting the distance between the front side member and the back side member.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773